

### DETAILED ACTION

1. Applicant's election of Group I, bis-piperidinyl compounds, with amendments to the claims limiting p and q to 1, filed on Nov. 20, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6, 13-15, 17 have been canceled. Claims 1-5, 7-12 and 18 are prosecuted. Claim 16 is withdrawn from consideration per 37 CFR 1.142(b).

As it was clearly instructed in the previous office action that for a process of use claim to be rejoined, it must be dependent entirely on the allowable scope of the allowable product *and to be free of all 112 issues*. Claim 16, as currently amended cannot be rejoined because it is evidenced by the art of record such as CA140:42193 that the anticipatory compounds do not share the same utility as the instantly claimed compounds thus, the bis-piperidinyl core is not the sole chemical structure for the claimed utility. In addition, the art recognized the many different function of the H3 receptor and no nexus or structural similarity was found between the instantly elected compounds and known compounds for any specific therapeutic efficacy (see Wijtmans et al.).

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter as not being not in a suitable form for publication. Please note that the claim requires reading or information from the specification to define the meets and bounds of the scope. There is no good reason why the structural delineation or the names of the compounds cannot be listed in the claims instead of using none chemical notation as E1-E120. Claims must, under modern claim practice, stand alone to define invention and incorporation into claims be express reference to specification and/or drawings is not permitted. Ex parte Fressola 27 USPQ2d 1608. It is recommended that either chemical structure or chemical name of the compounds be explicitly incorporated in the claim.

3. Claims 1-2, 12 and 18 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R1 being drawn to examples 1-120, does not reasonably

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provide enablement for the claimed scope wherein no limitation of the aryl, heteroaryl or heterocyclcyl were found. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The terms of the claims have taken into all chemistry with enormous aryl, heteroaryl or heterocyclic moieties. The reader has to conceive of the compound first, making the starting material and then synthesize the compounds which would be a life-time search project. The availability of the starting material other than examples 1-120 have not been provided but required. Without starting material, the term provided mere language rather than enablement. In addition, prior art of record such as US 2007/0037834 (CA140:42193 recited in the previous office action) clearly indicated that when R1 moiety is different from examples 1-120, but encompassed by the claims, the compounds are of a different utility. Given the broadest interpretation of the claims, the US 2007/0037834 reference would be a 102(f) or (g) reference. The breadth of the claims constitutes an enormous work loads that would require undue experimentation to find proper operative chemical entities for the claimed utility.

Especially, the compounds that have been tested (p.68) only for in vitro histamine H3 functional antagonist assay without nexus to the efficacy in any specific therapeutic functionality. In view of the lacking of structural similarity to the currently available histamine H3 binding compounds (see Wijitmans or Laurs et al. cited on 1449), the specification lacks sufficient support for pharmaceutical effective composition of the claimed compounds.

4. Claims 3-5, 7-9 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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*OACS/Chang*  
*Feb. 26, 2009*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*